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(71) Applicants and
(72) Inventors: YOUNG, Michael, John, Radley [GB/GB];
Bremridge House, Bremridge, Ashburton, South Devon
TQ13 7JX (GB). YOUNG, Stephen, Michael, Radley
[GB/GB]; Bremridge House, Bremridge, Ashburton,
South Devon TQ13 7JX (GB).

(74) Agent: GREGORY, Timothy, Mark; T M Gregory & Co,
26 Cyril Street, Northampton NN1 5EL (GB).

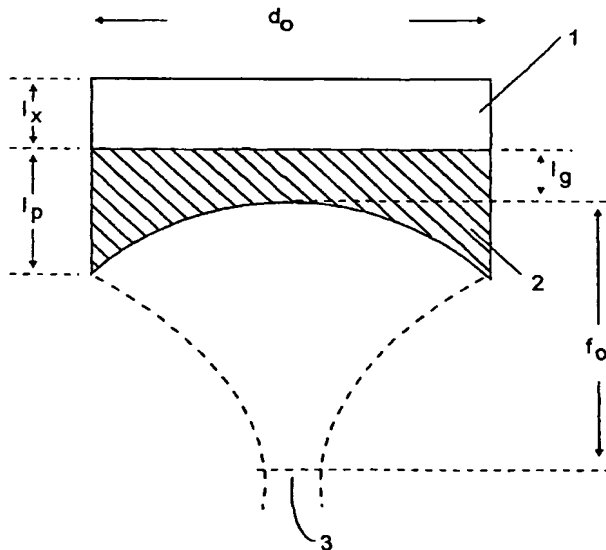
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(54) Title: METHOD AND APPARATUS FOR FOCUSSED ULTRASONIC ENERGY



(57) Abstract: The apparatus comprises an ultrasonic vibration generator (1) and a lens (2) affixed thereto adapted to focus the ultrasonic vibration at a predetermined zone. It may be used to destroy certain types of cancerous cell which lie close beneath the surface, such as skin cancers and other melanomas. Other cosmetic skin treatments may also be carried out, such as restructuring collagen molecules in order to tighten and restructure skin tissue, depilation and to destroy dyed tissue and thereby aid removal of unwanted tattoos.



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METHOD AND APPARATUS FOR FOCUSSED ULTRASONIC ENERGY

The present invention relates to a method and apparatus for focussing ultrasonic energy. The apparatus and method may be used, *inter alia*, for treatment of tissue, especially subcutaneous tissue, utilising non-invasive focussed ultrasound.

The term focussing when applied to sound waves has subtly different meanings from the generally understood principles surrounding optical focussing. A light beam is focussed by a lens so that a planar beam of light is directed to a point of convergence (and subsequent divergence). In this case the lens is not affected by the electromagnetic beam as it travels through the device.

Ultrasound is generated by a vibrating device. If the device is a curved piezo-electric transducer crystal then the curved surface of the crystal emits a sound wave propagating normally to the surface. This wave converges over a common region. The essential difference between the optical and the ultrasonic is that the distance of the point of

convergence of the sound wave from the "lens" is dependent upon the mode of resonance in the vibrating device. The case of a curved piezoelectric ceramic transducer (PZT) crystal is relatively simple, since essentially only a single mode of resonance should be possible.

However, a piezo ceramic generator and a focussing element may be deliberately close-coupled, using some form of epoxy or other cement. When this approach is taken, the simple theory is inadequate to predict focal plane position and beam intensities. Errors of up to 50% are apparent when determining the properties of small diameter acoustic lenses.

If a disc PZT is bonded to a disc of metal to produce a combination transducer, then multiple modes of resonance become possible, and the effects of changes in mode are extremely complex. In very general terms, if the free face of the metal disc is given a convex radius then most modes of resonance result in a radiating beam, i.e. divergent. Conversely, if the free face of the metal disc is given a concave radius then the transmission path of the "beam" will reduce in diameter, before subsequently increasing. This convergence will vary with the mode of resonance in degree, in the minimum diameter of the transmission path attained, and in its position from the lens.

Finite element techniques can accurately model complex physical systems which consist of two or more solid materials and an essentially fluid phase representing a target material. If it is possible to determine the transducer/lens geometry to achieve particular focussing characteristics, it will greatly simplify the task of designing and building focussed arrays of transducers with combined lens systems.

The finite element model may be used to predict the geometry of axisymmetric lens transducer combinations taking into account all factors affecting the vibrational modes generated in the solid components of the system. The analytical mesh may be extended into the fluid phase to generate beam shape and confirm the focussing characteristics of the device.

Curved PZT transmitters (operating in the MHz bands) are used in various medical applications, but they suffer from at least two inherent limitations. They are expensive to produce and they are essentially fragile.

The former problem is simply a function of the production process. The latter arises from the high output requirements for medical applications and the minimal thickness of the ceramic in order to achieve resonance at MHz frequencies.

Systems are known from our Patent Application No GB 2367500A in which a lens is disposed adjacent to a PZT. However, the focussing of such systems has been found to be difficult since the approach taken has not appreciated the complexity of the problem.

Combination transducers, i.e. transducers having a lens firmly attached to the PZT, should point towards a single solution to these problems. Firstly, flat disc PZTs are a fraction of the cost of curved ceramics, and may be produced in all possible dimensions. Secondly, bonding a flat PZT to an aluminium plate, using epoxy adhesive, results in a highly durable system.

Such combination transducers can be further improved by curving a face of the lens plate. However the focussing of such transducers is much more complex than has hitherto been thought.

It is therefore an object of the invention to provide a combination lens giving improved beam focussing.

In general, tissue which may be treated by the method and using the apparatus includes subcutaneous blood vessels, unsightly thread veins, selected cancer tissue, and the like. The apparatus may be used for haemostatic cutting and cauterising of blood vessels. It may also be used in other, non-medical, areas where it is desired to apply high intensity energy to a small target zone.

One tissue type which may benefit from such treatment comprises fine arteries and veins lying closely beneath the dermis. These may become visible in quite random areas, and where they are visible through the dermis in a localised area, these arteries or veins may constitute a serious visual skin blemish, known sometimes as "spider veins."

It is known to remove or treat such blood vessels either using laser energy or by forms of invasive surgery so that the blood supply to that particular part of the vascular system is permanently interrupted and the unsightly blemish may be removed.

However, such known methods of treatment may cause collateral damage to the tissue of the patient being treated or may require lengthy recovery periods.

Similarly, it is well known that certain types of cancerous cell may lie close beneath the surface, such as skin cancers and other melanomas. Such cancers can sometimes be treated by means of laser irradiation, but there may again be damage to surrounding tissue and to the outer layers of the dermis and this may be unacceptable.

Cosmetic skin treatments may also be carried out in similar ways.

Collagen molecules may be restructured in order to tighten and restructure skin tissue, using a focussed beam.

Depilation may presently be carried out by painful treatments such as electrolysis, or temporarily by waxing, shaving or plucking. A beam of energy focussed on each follicle would destroy the hair and prevent further growth.

A focussed beam may also be used to destroy dyed tissue and thereby aid removal of unwanted tattoos.

It is thus a further object of the present invention to provide a method and apparatus for treatment of surface or subcutaneous tissue which obviates the above disadvantages.

According to a first aspect of the present invention, there is provided an apparatus for focussing a beam of ultrasonic vibration comprising means to generate ultrasonic vibrations and lens means affixed to said generating means and adapted to focus said ultrasonic vibration at a predetermined zone.

The lens means may be plano-concave.

The lens means may comprise titanium, titanium alloy, aluminium, aluminium alloy, or a mixture containing such materials.

The lens means may comprise a plurality of individual lens facets.

In this case, the plurality of individual lens facets may be affixed to a single generating means.

At least some of said facets may have a substantially coincident centre of their radius of curvature.

At least some of said facets may have a substantially coincident focal point or zone.

The lens means may be divided into a series of substantially annular zones each of material having a different wave velocity.

The apparatus may be applied to treatment of a zone of tissue on or beneath the dermis.

According to a second aspect of the present invention, there is provided a method of treatment of tissue comprising the steps of providing an apparatus as described above, having such pre-selected characteristics that the energy is focussable on the zone to be treated, and applying said apparatus to a body within which lies the tissue to be treated.

In order to treat skin blemishes, the tissue to be treated may be subcutaneous blood vessels.

In a cosmetic depilation method, the tissue to be treated may be hair follicles.

In a cosmetic tattoo removal method, the tissue to be treated may be stained skin cells.

Embodiments of the present invention will now be more particularly described by way of example and with reference to the accompanying drawings, in which:-

Figure 1 shows schematically a system for generating focused ultrasound;

Figure 2 shows schematically in end elevation a system for generating high intensity focused ultrasound;

Figure 3 shows schematically and in cross-section the system of Figure 2;

Figures 4A and 4B shows schematically, in elevation and in cross section a composite system incorporating differential phase shift lens;

Figure 5 shows 3D plot of pressure amplitude up to 36mm from the lens surface over half the radiatory surface, i.e. 12.5mm from centre line;

Figure 6 shows graphically pressure variation along the lens axis showing peak intensity 8mm from the lens surface;

Figure 7 shows graphically radial variation of intensity of the focal plane;

Figure 8 shows 3D plot of pressure amplitude up to 36mm from the lens surface over half the radiatory surface, i.e. 12.5mm from centre line;

Figure 9 shows graphically pressure variation along the lens axis showing peak intensity 27mm from the lens surface; and

Figure 10 shows graphically radial variation of intensity of the focal plane.

Examples of apparatus embodying the invention are given below, by way of example and with reference to Figure 1 of the drawings.

In the Examples,

l_p represents the thickness of the lens at its periphery;

l_c represents the thickness of the lens along its axis;

d_o represents the diameter of the lens; and

R represents the radius of curvature of the concave face of the lens.

Referring now to Figure 1 of the drawings, a piezoelectric ceramic disc 1 is adapted to produce high frequency ultrasound in the 1 – 5 MHz range when excited at an appropriate frequency by electrical means (not shown). Immediately adjacent to the piezoelectric ceramic disc 1, and affixed thereto by appropriate adhesive means, is a focusing plano-concave lens 2 of aluminium alloy, titanium alloy or other suitable material or mixture, whereby the ultrasonic vibration is directed to a focal zone 3 within the body wherein is located tissue to be treated.

Example 1.

An apparatus useful at a frequency in the region of 1.57MHz had lens dimensions as follows:

$$l_p = 4.0\text{mm}$$

$$l_c = 1.5\text{mm}$$

$$d_o = 10\text{mm}$$

giving an apparatus having a focal length of 7.0mm and a focal area of 0.02cm^2 .

Example 2.

An apparatus useful at a frequency in the region of 1.55MHz had lens dimensions as follows:

$$\begin{aligned}l_p &= 3.5\text{mm} \\l_c &= 1.5\text{mm} \\d_o &= 10\text{mm} \\R &= 7.5\text{mm}\end{aligned}$$

giving an apparatus having a focal length of 10.0mm and a focal area of 0.025cm².

Example 3.

An apparatus useful at a frequency in the region of 1.57MHz had lens dimensions as follows:

$$\begin{aligned}l_p &= 4.0\text{mm} \\l_c &= 1.5\text{mm} \\d_o &= 10\text{mm} \\R &= 6.26\text{mm}\end{aligned}$$

giving an apparatus having a focal length of 7.6mm and a focal area of 0.02cm².

Referring now to Figures 2 and 3, a single piezoelectric ceramic transducer, preferably of diameter 35mm, is attached to a complex lens 5, of thickness preferably 12-13mm at its periphery and in the region of 8mm at its thinnest point.

The outer surface of the lens 5 is formed to have four equiangularly spaced concavities 6. Each forms part of a sphere, with the radii of curvature meeting at a preselected point.

More or less than four concavities 6 may be provided.

Further Examples of theoretical determination of lens characteristics are given below:

Example 4.

Results for a physical system of conjoined lens and PZT where:

Thickness of PZT disc - $l_1 = 2\text{mm}$

Thickness of lens at periphery - $l_2 = 7.5\text{ mm}$

Thickness of lens at axis - $l_3 = 1.5\text{ mm}$

Radius of curvature of lens face - $R = 15.25\text{ mm}$

Diameter of assembly - $D = 25\text{ mm}$

are shown in Figures 8 to 10, where:

Figure 8 shows 3D plot of pressure amplitude upto 36mm from the lens surface over half the radiatory surface, i.e. 12.5mm from centre line;

Figure 9 shows pressure variation along the lens axis showing peak intensity 27mm from the lens surface; and

Figure 10 shows radial variation of intensity of the focal plane.

Example 5

Results for a physical system of conjoined lens and PZT where:

Thickness of PZT disc - $l_1 = 2\text{mm}$

Thickness of lens at periphery - $l_2 = 4\text{ mm}$

Thickness of lens at axis - $l_3 = 1.5\text{ mm}$

Radius of curvature of lens face - $R = 6.25\text{ mm}$

Diameter of assembly - $D = 10\text{ mm}$

are shown in Figures 5 to 7, where:

Figure 5 shows 3D plot of pressure amplitude upto 36mm from the lens surface over half the radiatory surface, i.e. 12.5mm from centre line;

Figure 6 shows pressure variation along the lens axis showing peak intensity 27mm from the lens surface; and

Figure 7 shows radial variation of intensity of the focal plane.

The beam cross section determined experimentally closely matches the theoretically predicted pattern.

When a PZT transducer element is mechanically attached to a focussing device, a complex resonator is created which can only be analysed in its operating mode using sophisticated finite element techniques. Such methods have been refined to permit detailed analysis of the dynamic wave patterns transmitted from close coupled duplex focussing transmitters which consist essentially of a plain disc PZT transducer, bonded to a plano-concave metal lens. The theory considers the geometry and acoustic properties of the duplex focussing device and simulates its operation when transmitting into fluid media over a wide range of frequencies. Such devices operate more like axial or radial resonators in longer wavelength systems and involve distortion of the lens which does not occur in optical systems. This technique allows specific focussing characteristics to be selected to satisfy the energy and geometrical requirements of a wide range of surgical procedures.

Measurements were made in a beam plotting tank, in which a hydrophone is suspended within a volume of water into which an ultrasound device transmits. The hydrophone is accurately positioned relative to the transmitter, in three dimensions, using Vernier drives. The sensor measures the pressure developed by the travelling wave passing through the water, and converts this into a voltage signal; this is then plotted on a PC to produce a record of the transmission path shape. The width of the transmission path can be measured at known distances from the centre of the lens, allowing the calculation of the position of the minimum width, i.e. the "focal point"; and the degree of "focus", the ratio of lens surface area, and area of the transmission path at the "focal" plane.

The material used for the lens was aluminium, for the ease of machining and good acoustic properties, and for the bond - standard Araldite (RTM) epoxy adhesive.

The empirical investigation of lens geometry was carried out in two phases, based on the diameter of the PZT's employed. The previously developed ultrasonic radiating devices utilise 10mm diameter discs, thus the initial range of lenses were based on Ø10mm aluminium discs with one face given a concave machined radius of curvature. The initial radii chosen were intended to cover a representative range, and are listed in the table below.

Table 1 (all dimensions in mm)

Radius	Minimum Thickness (T_L^{Min})	Maximum Thickness (T_L^{Max})
6.25	1.5	4.0
20.0	2.5	3.14
∞ (Flat)	3.0	3.0
7.0	1.5	3.601
7.5	1.5	3.410
8.0	1.5	3.255

The smallest radius of curvature was derived by taking the half-wavelength at 1 MHz in aluminium (which is $\sim 2.5\text{mm}$) and making this the depth of the concave surface. This meant that if the minimum thickness was also 2.5mm , then theoretically the greatest amplitude at the lens surface would be shown both at the centre and extremity of the surface. The radius of 6.25mm was simply the result of fixing these dimensions.

Various values of minimum thickness were examined for the first three radii of curvature, but only those listed in Table 1 showed noteworthy results, see Table 2. In light of these results the second three lens types were examined in order to investigate the apparent progress shown by the R6.25 (i.e. 6.25mm radius of curvature) types.

Table 2 (all dimensions in mm)

Radius	f/MHz	Acoustic Output/mg ¹	Focal Length	Transmission Path Ø	Focussing Factor ²
6.25	1.55	0 to 3	7.7	1.9	35.91
20.00	1.561	3	12	3.3	9.33
20.00	1.605	6	13	2.8	12.96
∞ (Flat)	1.242	4	6	6.2	2.6
7.00	1.57	0 to 3	8	1.9	32.54
7.50	1.55	0	10	1.8	35.43
8.00	1.562	-	7	5.6	3.58

¹ Force Balance measurement² Ratio of area of Transmission Path at Focal Plane to surface area of Lens

The first point to note is the small values obtained for Acoustic Output. This is due to two factors. Firstly, the crystals are “tuned” to a natural frequency of 1MHz, thus the modes of resonance giving required characteristics are “off-resonance”, insofar as they are not at the natural resonant frequency of the systems. This results in poor energy transfer from the generator. Consequently, the generator should be optimised for the loads specific electrical characteristics, allowing modes of resonance not at the natural resonant frequency to be efficiently driven.

The only example of the first group of lenses showing pronounced reduction in Transmission Path Diameter was the R6.25 lens with a minimum thickness of 1.5mm; those examples not listed failed to show a significant degree of “focus”. Whilst the marginal levels of “focus” shown by the R20 (i.e. 20mm radius of curvature) and Flat examples are not in themselves impressive, they suggested a decrease in the desired characteristics with increasing radius of curvature. Most interestingly of all, the Flat lens still appears to illustrate a modicum of “focus”.

These results suggest a diffraction mechanism for the reduction in Transmission Path Diameter. The “focus” shown by the Flat lens may be attributed to a near field effect where destructive and constructive interference between waves transmitted from the surface produce a resultant converged path. The mechanism by which the greater decreases in Transmission Path Diameter are attained are also likely to be based on an interference form, in which case the decrease in radius was responsible for an amplification of this effect.

In order to assess this premise, a second series, this time of Ø10 (10mm diameter) lenses, was produced. These investigated the effects of smaller increases in radius from the “optimum” R6.25 form. The results appear to show that a similar level of “focus” can be attained, but that it has a limit, reached with a radius of around 8.0mm, at which no resonant frequency showed a similarly pronounced “focus”.

The following conclusions may be drawn:

- The minimum thickness of the lens is preferably approximately 1.5mm.

- The radius of curvature of the lens and diameter of the disc should result in a pronounced depth to the lens.
- A generator should be capable of optimal matching to modes other than to the natural frequency of the transducer, since modes of resonance providing the required characteristics are not necessarily coincident with the natural resonant frequency.

These conclusions led to a second phase of the empirical investigation. Ø25 (25mm diameter) PZT's were affixed to a range of aluminium lenses machined with radii of curvature shown below.

Table 3 (all dimensions in mm)

Radius	Minimum Thickness (T_L^{Min})	Maximum Thickness (T_L^{Max})
15.625	1.5	7.753
17.5	1.5	6.753
20.0	1.5	5.888

These transducers were investigated in the prescribed manner, the results being listed in Table 4.

Table 4 (all dimensions in mm)

Radius	f/MHz	Acoustic Output/mg ¹	Focal Length	Transmission Path Ø	Focussing Factor ²
15.625	1.232	155	19	2.1	177.38
15.625	1.242	285	23	1.8	241.18
15.625	1.334	120	12.5	3.8	54.12
17.50	1.405	130	20	2.1	166.92
20	1.255	180	24	4.2	39.81
20	1.436	35	24	2.0	175.59
20	1.492	10	22	2.1	159.35

¹ Force Balance measurement

² Ratio of area of Transmission Path at Focal Plane to surface area of Lens

The results listed in Table 4 show a dramatic increase in “focus” over those values measured for the Ø10 series of transducers. The increased acoustic output of the systems, compared to earlier, is also noticeable.

The levels of “focus” measured are of the order needed to reach the intensities required to achieve denaturing in mammalian tissue. This achievement was the initial requirement to move on to identify the levels of Heat Generator in samples of “model” absorbing material.

The experimental technique and principal of the set-up is quite simple. The transmitter being assessed is inserted into a lower holding tube, to a known depth. Water is injected into the

space between the lens and the membrane covering the tube, all air being removed via a second tube/syringe. The upper portion of the system is mounted against the lower. The sample holder, containing the chosen absorbing material held in by a second membrane, is screwed down to the required height. Acoustic coupling gel acts as a lubricant between the two membranes and limits losses. The thermocouple holder is inserted into the top of the sample holder to measure initial temperature, it is then removed, the transducer activated for a fixed time, and the thermocouple re-introduced to measure the temperature rise due to the insonation. (Ambient temperature is simultaneously monitored as a control).

The results, for absorption of energy transmitted from the Ø25, R15.625, T_L^{Min} 1.5 transducer, obtained in triethylene glycol (TEG), liver and a mixture of the two, are presented below.

Table 5

Absorbing Material	Distance/mm ¹	Temperature Increase/°C
TEG	23	19
Liver(water)	18	12
Liver(TEG)	18	14

¹Distance from centre of lens to interface of membranes.

These results quoted are not the complete picture. The pattern of temperature rise, over a range of distances from the lens, does not smoothly rise to a maximum and then recede, it

goes through a number of peaks and troughs. This is almost certainly due to the complicated nature of the transmission within the experimental cell.

The nature of the material noted in Entry 1 allows an energy balance to be carried out whereby a measure of the efficiency of the process can be measured:

$$\begin{aligned}
 \text{Acoustic Output from Transducer} &= 0.285/0.0688 = 4.142\text{W} \\
 \text{Energy Transmitted during 5s insonation} &= 4.142 \times 5 = 20.71\text{J} \\
 \text{Average Energy Absorbed by TEG} &= 2.4 \times 0.5625 \times 15 \\
 &= 20.25\text{J} \\
 \text{Efficiency of Insonation Process} &= 20.25/20.71 = 97.8\%
 \end{aligned}$$

Thus, TEG is an excellent test material for assessment of Acoustic Absorption.

In order to optimise the focussing effect of the close coupled generators, the propagation of wave energy from all parts of the concave output face should be directed substantially towards the generator axis, and each surface element of the concave radiating face should experience a displacement which is substantially in-phase with all neighbouring elements, in both circumferential and radial directions.

These criteria can be met by consideration of the fact that different materials have individual acoustic properties, and the requisite level of control can be achieved by appropriate selection of materials.

Referring now to Figure 4A, there is shown a device in which the plano-concave lens comprises a plurality of annular sections (B,C, D, E) surrounding a central circular section

(A). Each section is of a material having complimenting properties so that the wave from the planar face, contacting the PZT disc, will be transmitted from the concave radiating face 8 in an optimum manner.

The device shown in Figures 4A and 4B has concentric sections A, B, C, D and E, consisting of different materials each displaying an appropriate phase velocity constant, and separated by tubes 7 of an isolating material, for example PTFE. The elements of the concave, radiating surface 8 are adapted to meet the above criteria, *i.e.* with in-phase convergent waves transmitting from surface 8. Table 6, below shows by way of example materials and their arrangement to give increasing phase velocity from the inner to the outer elements to compensate for the increase in thickness across the lens.

Table 6.

Element	Material	Acoustic Velocity/ cms^{-1}
A	Aluminium Bronze	4.07
B	K-Monel	4.3
C	Ti Alloy	4.78
D	Alumina	5.01
E	Stainless Steel	5.16

Optimum drive frequencies and annular widths consistent with a particular focussing radius can be determined.

The advantages of this method of construction and design of the apparatus include:

1. Increased mechanical strength of the PZT lens structure.
2. Higher energy output per unit size.
3. Greater design flexibility.
4. Reduced unit cost.
5. Use of multi-head systems to create unique beam shapes.

CLAIMS

1. An apparatus for focussing a beam of ultrasonic vibration comprising means to generate ultrasonic vibrations and lens means affixed to said generating means and adapted to focus said ultrasonic vibration at a predetermined zone.
2. An apparatus as claimed in claim 1, wherein the lens means is plano-concave.
3. An apparatus as claimed in either claim 1 or claim 2, wherein the lens means comprises titanium, titanium alloy, aluminium, aluminium alloy, or a mixture containing any one or more of such materials.
4. An apparatus as claimed in any one of the preceding claims, wherein the lens means comprises a plurality of individual lens facets.
5. An apparatus as claimed in claim 4, wherein the plurality of individual lens facets is affixed to a single generating means.
6. An apparatus as claimed in either claim 4 or claim 5, wherein at least some of said facets have a substantially coincident centre of their radius of curvature.
7. An apparatus as claimed in any one of claims 4 to 6, wherein at least some of said facets have a substantially coincident focal point.

8. An apparatus as claimed in any one of the preceding claims, wherein the lens means is divided into a series of substantially annular regions each of which comprises material having a wave velocity different from that of adjacent regions.
9. A method of treatment of tissue comprising the steps of providing an apparatus as claimed in any one of claims 1 to 8 having such pre-selected characteristics that the energy is focussable on a zone of tissue to be treated, and applying said apparatus to a body within which lies said zone.

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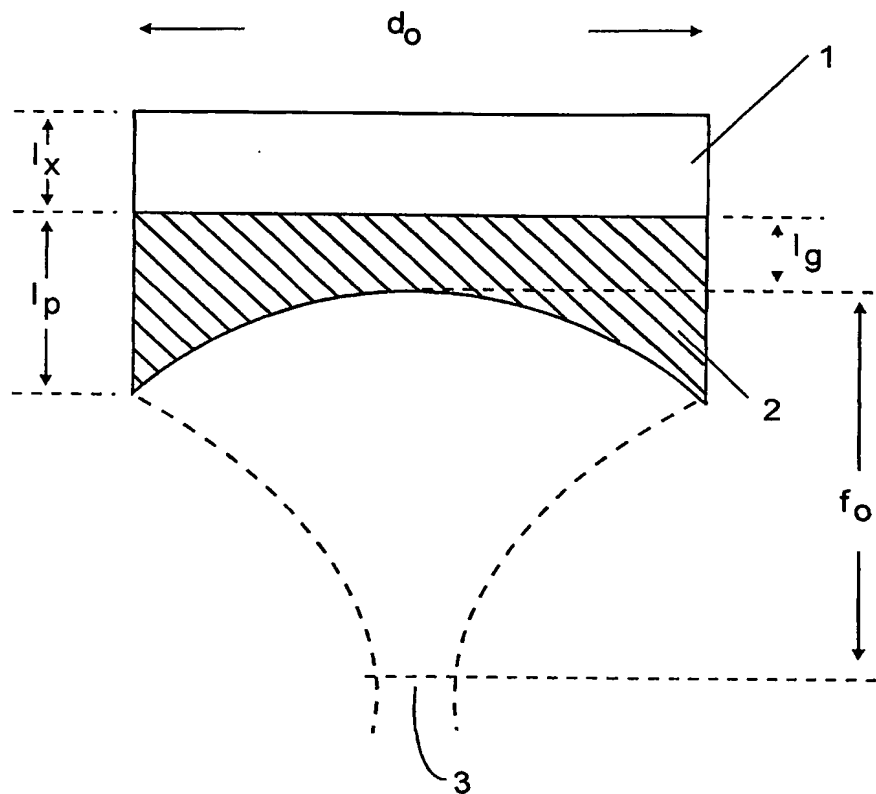


FIG 1

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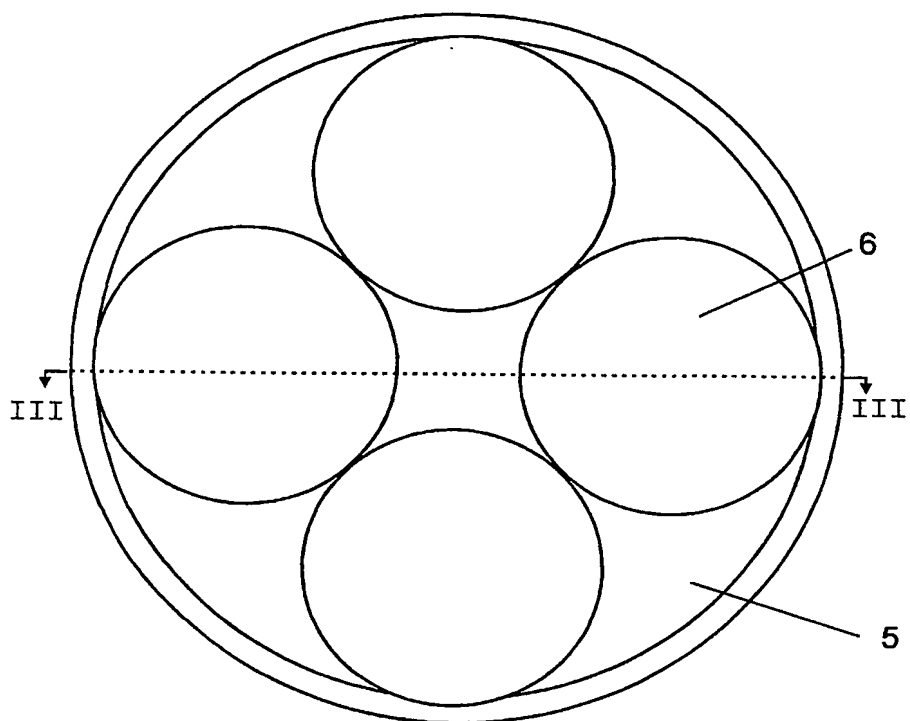


FIG 2

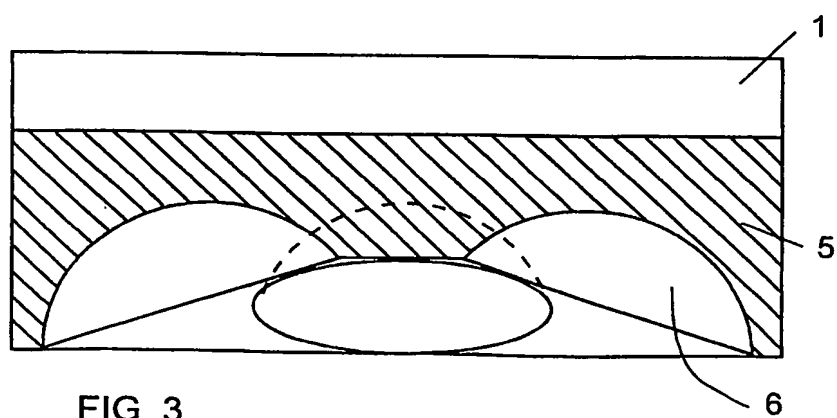


FIG 3

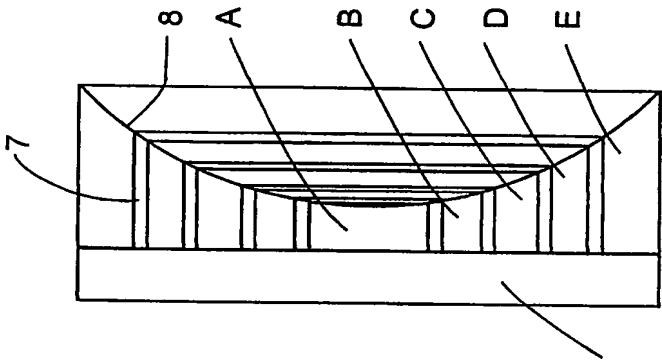


FIG 4B

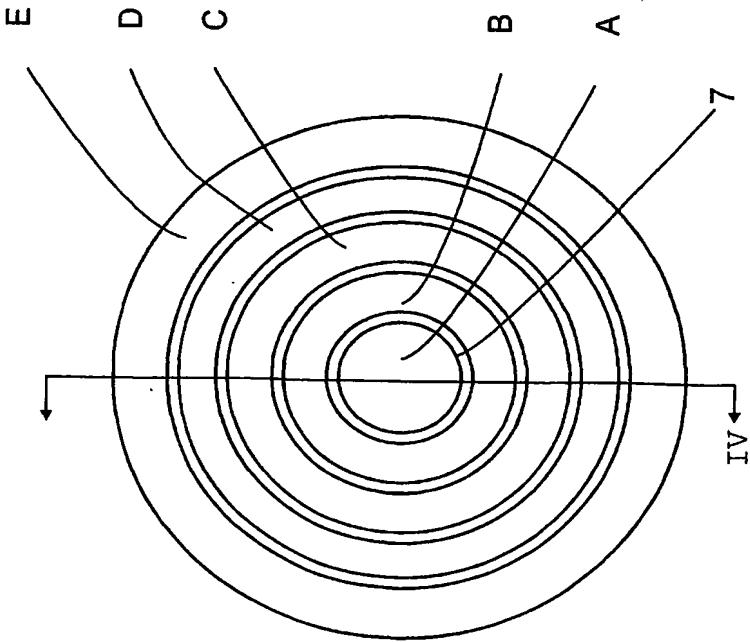


FIG 4A

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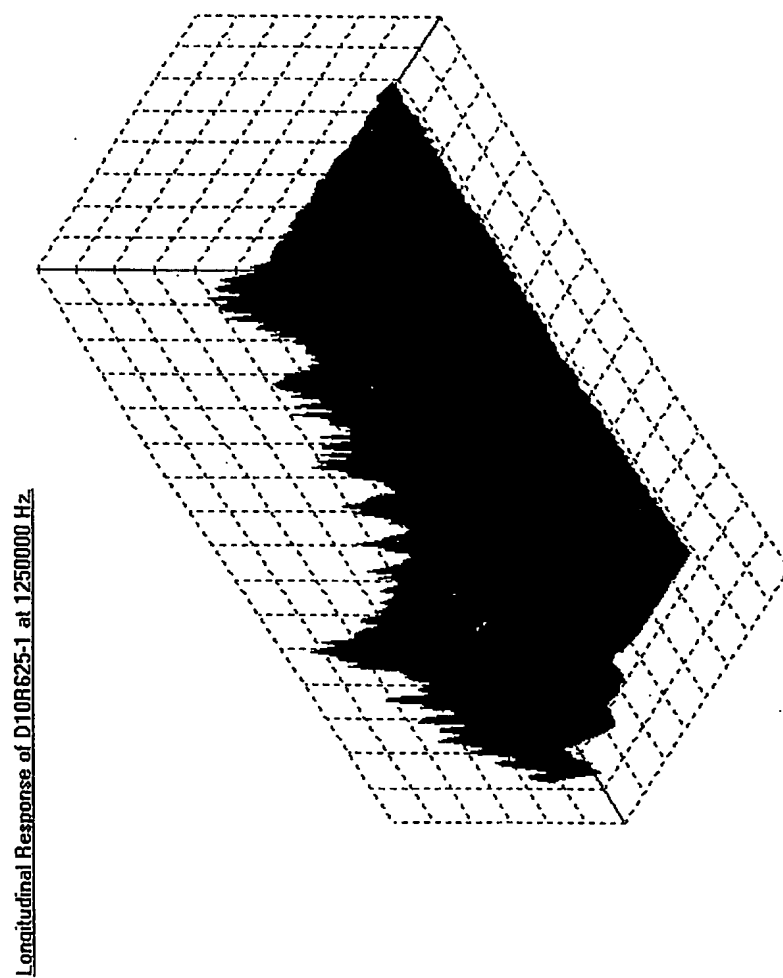


Fig 5

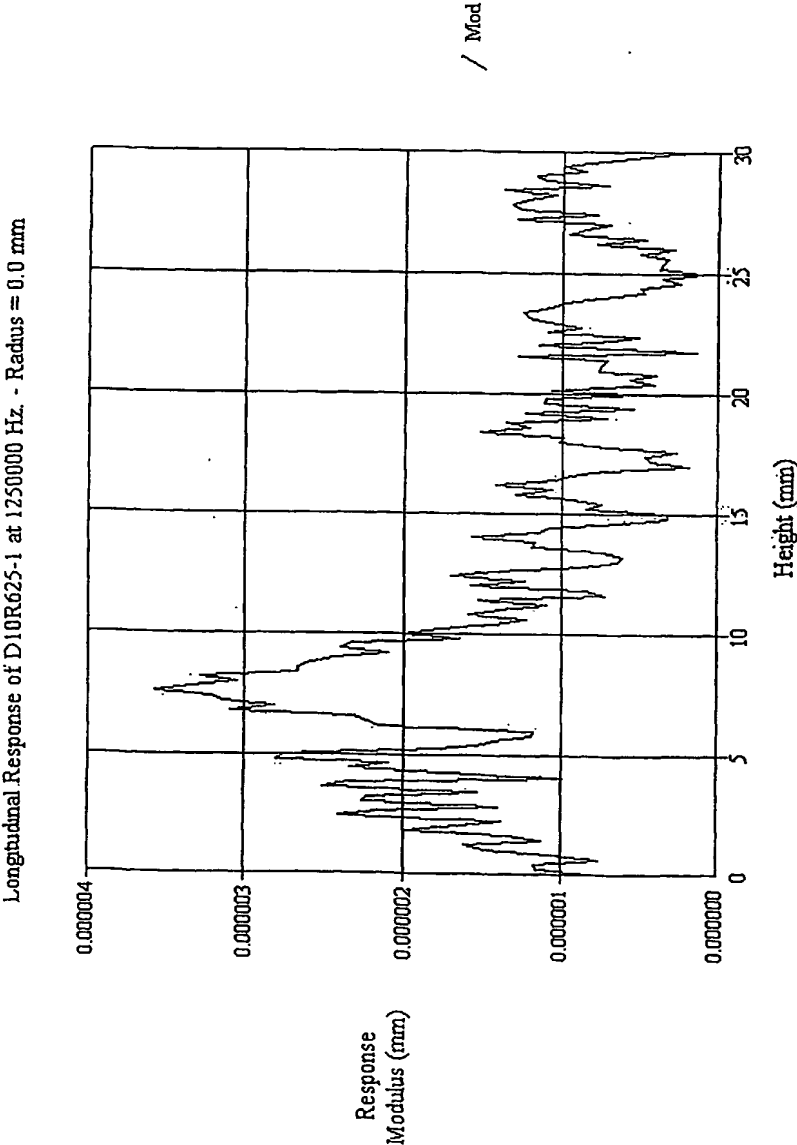


Fig 6

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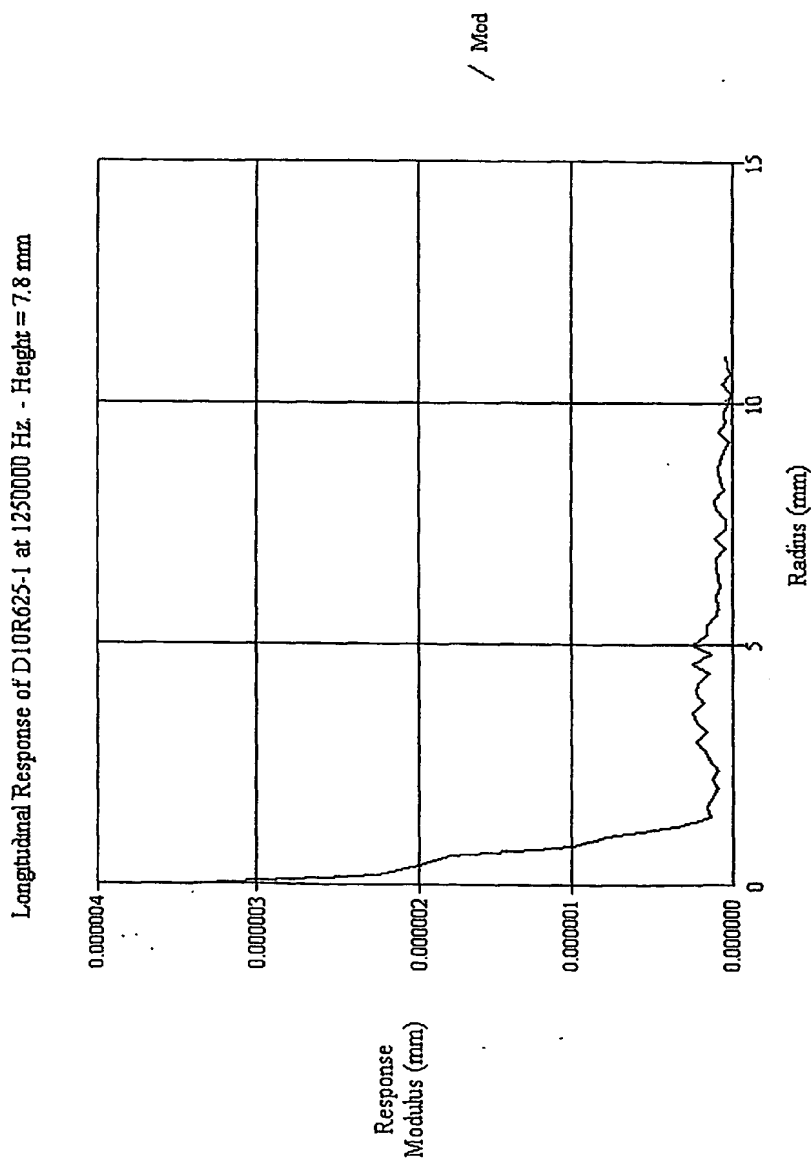


Fig 7

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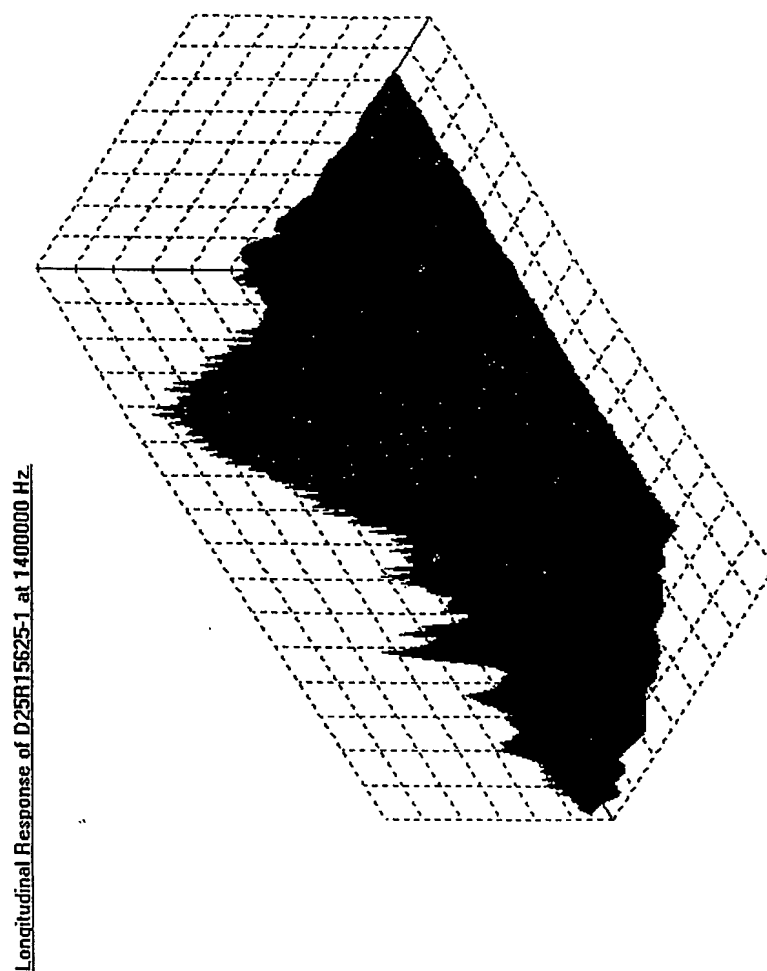


Fig 8

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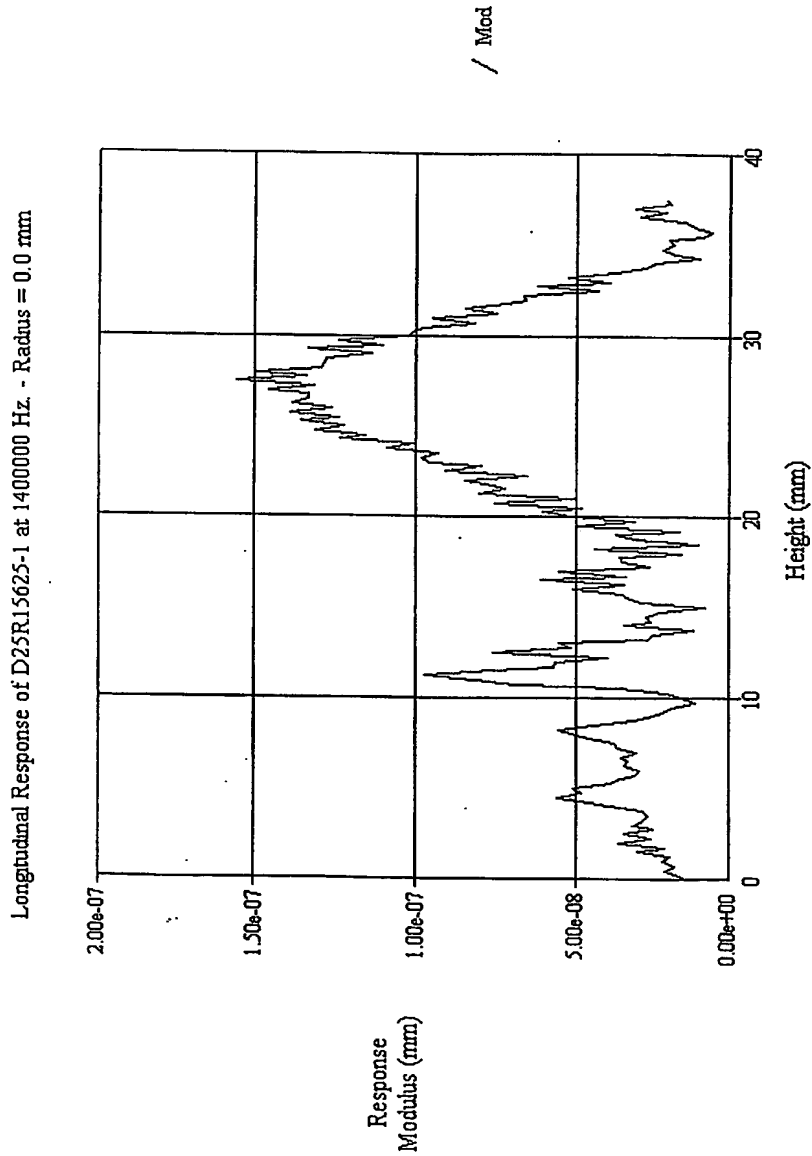


Fig 9

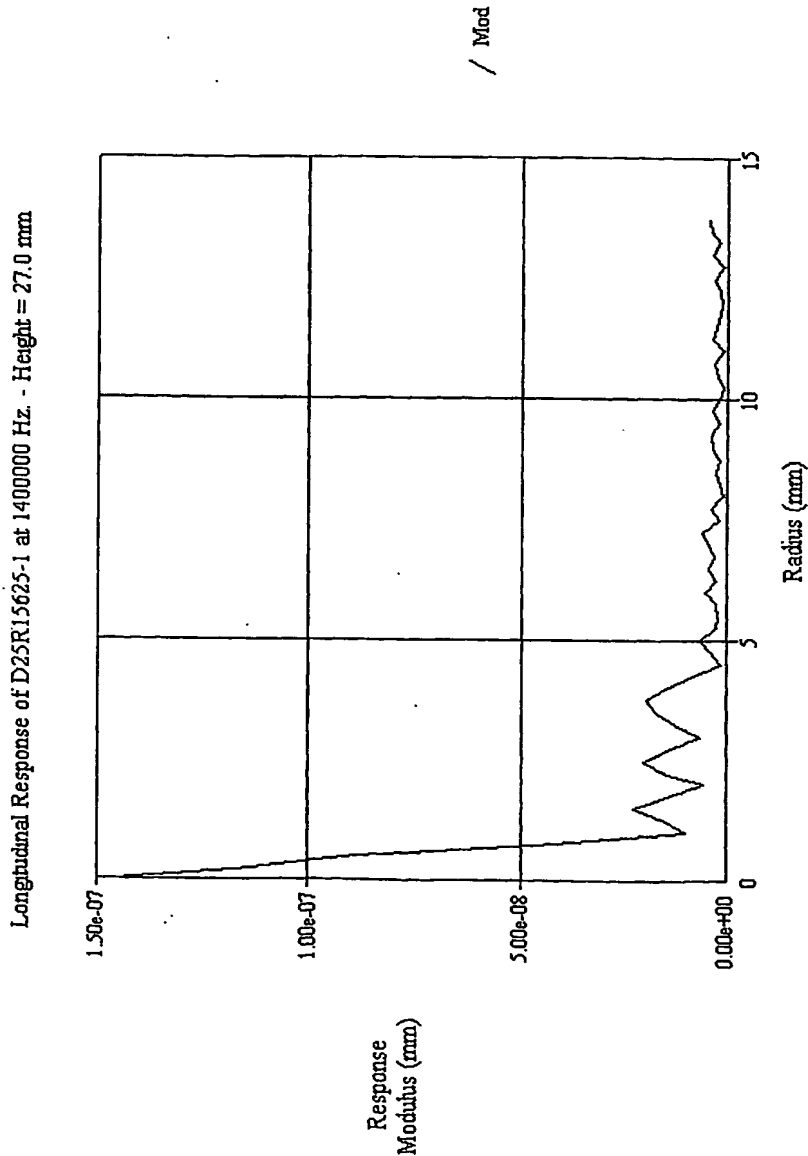


Fig 10

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 03/00349

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 G10K11/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G10K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 02055 A (YOUNG MICHAEL JOHN RADLEY ;YOUNG STEPHEN MICHAEL RADLEY (GB)) 11 January 2001 (2001-01-11) page 4, line 14 - line 19; figure 1 ---	1-3
A	US 2001/023326 A1 (SPECTOR AVNER) 20 September 2001 (2001-09-20) page 8, column 2, paragraph 218; figure 7 ---	4,5,7,8
A	US 3 903 990 A (TANNAKA YASUAKI) 9 September 1975 (1975-09-09) column 2, line 53 -column 3, line 10; figures 2-4 ---	4,5,7,8
A	US 6 200 491 B1 (ZESCH JAMES C ET AL) 13 March 2001 (2001-03-13) column 3, line 33 - line 59; figures 1,2 --- -/--	4

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

A document member of the same patent family

Date of the actual completion of the international search

27 June 2003

Date of mailing of the international search report

04/07/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Anderson, A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 03/00349

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 4 044 273 A (KANDA HIROSHI ET AL) 23 August 1977 (1977-08-23) figure 5</p> <p>-----</p>	1

INTERNATIONAL SEARCH REPORT

national application No.
PCT/GB 03/00349

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 9
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery; Claim 9 describes a method of treatment of tissue using the apparatus as claimed in Claim 1
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-3

Ultrasonic transducer having a plano-concave lens made from titanium or aluminium

2. Claims: 4-7

A single transducing element having an acoustic lens which comprises a plurality of individual lens facets

3. Claim : 8

Ultrasonic transducer having a lens which is divided into a series of annular regions

INTERNATIONAL SEARCH REPORT

information on patent family members

Int. Application No

PCT/GB 03/00349

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